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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CATALYST PHARMACEUTICALS, INC., Plaintiff, v. MSN LABORATORIES PRIVATE LIMITED and MSN PHARMACEUTICALS INC., Defendants.	Civil Action No. _____ (Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Catalyst Pharmaceuticals, Inc. ("Catalyst"), by its undersigned attorneys, for its Complaint against Defendants MSN Laboratories Private Limited ("MSN Labs") and MSN Pharmaceuticals ("MSN Pharma") (collectively, "Defendants"), allege as follows:

NATURE OF THIS ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, arising from Defendants' submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 218152 ("Defendants' ANDA") seeking approval to engage in the commercial manufacture, use, or sale of a generic version of Catalyst's Fycompa® (perampanel) 0.5 mg/mL oral suspension drug product ("Defendants' ANDA Product") prior to the expiration of United States Patent Nos. 8,772,497 ("the '497 patent" or "the Patent-in-Suit").

PARTIES

2. Plaintiff Catalyst is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 355 Alhambra Circle, Suite 801, Coral Gables, Florida 33134. Catalyst is a commercial-stage biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases.

3. On information and belief, Defendant MSN Labs is a corporation organized and existing under the laws of India, having a principal place of business at MSN House, Plot No: c-24, Industrial Estate, Sanathnagar, Hyderabad – 18, Telangana, India.

4. On information and believe, Defendant MSN Pharma is a Delaware corporation having a principal place of business at 20 Duke Road, Piscataway, New Jersey, 49754.

5. On information and belief, MSN Pharma is a wholly-owned subsidiary of MSN Labs and is an authorized U.S. Agent for MSN Labs, including for MSN's ANDA.

JURISDICTION AND VENUE

6. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. On information and belief, MSN Labs derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

8. This Court has personal jurisdiction over MSN Labs because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in the State of New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, MSN Pharma, a company with a regular and established place of business in New Jersey; and (2) maintains extensive and systematic contacts with the State of New Jersey, including through the marketing, distribution, and/or sales of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, MSN Pharma.

9. On information and belief, MSN Pharma derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

10. This Court has personal jurisdiction over MSN Pharma because, *inter alia*, it: (1) on information and belief, maintains a regular and established, physical place of business at 20 Duke Road, Piscataway, New Jersey, 49754; (2) has purposefully availed itself of the privilege of doing business in the State of New Jersey; and (3) maintains extensive and systematic contacts with the State of New Jersey, including through the marketing, distribution, and/or sale of generic

pharmaceutical drugs in New Jersey. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over MSN Pharma. On information and belief, MSN Pharma purposefully has conducted and continues to conduct business in this Judicial District.

11. On information and belief, MSN Labs and MSN Pharma are in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, MSN Labs and MSN Pharma also prepare and/or aid in the preparation and submission of ANDAs to FDA, including Defendants' ANDA.

12. On information and belief, this Judicial District is a likely destination for Defendants' ANDA Product described in Defendants' ANDA.

13. This Court also has personal jurisdiction over MSN Labs and MSN Pharma because, *inter alia*, they have committed an act of patent infringement under 35 U.S.C. § 271(e)(2). On information and belief, MSN Labs and MSN Pharma intend a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Catalyst in New Jersey and in this Judicial District.

14. In the alternative, this Court has personal jurisdiction over MSN Labs because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Catalyst's claims arise under federal law; (b) MSN Labs is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) MSN Labs has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over MSN Labs satisfies due process.

15. On information and belief, MSN Labs and MSN Pharma work in privity and/or concert either directly or indirectly through one or more of their wholly owned subsidiaries with respect to the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

16. On information and belief, each of MSN Labs and MSN Pharma actively participated in the submission of Defendants' ANDA. On information and belief, MSN Labs and MSN Pharma will work in privity and/or concert with one another and/or other related entities towards the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including Defendants' ANDA Product, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the Patent-in-Suit.

17. On information and belief, MSN Labs intends to benefit directly if Defendants' ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Defendants' ANDA Product that is the subject of Defendants' ANDA.

18. On information and belief, MSN Pharma intends to benefit directly if Defendants' ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Defendants' ANDA Product that is the subject of Defendants' ANDA.

19. On information and belief, MSN Pharma acts at the direction, and for the benefit, of MSN Labs and is controlled and/or dominated by MSN Labs.

20. On information and belief, MSN Labs and MSN Pharma act, operate, and/or hold themselves out to the public as a single integrated business.

21. Defendants have invoked the jurisdiction of the courts of this Judicial District as counterclaim plaintiffs in numerous patent infringement actions under the Hatch-Waxman Act. *See, e.g.*, *Bausch Health Ireland Ltd., et al., v. MSN Labs. Private Ltd*., *et al*., C.A. No. 21-10057, ECF No. 10 (D.N.J. June 18, 2021); *Mitsubishi Tanabe Pharma Corp., et al., v. MSN Labs. Private Ltd., et al.*, C.A. No. 19-18958, ECF No. 11 (D.N.J. Dec. 6, 2019); *Chiesi USA Inc., et al., v. MSN Pharms. Inc., et al*., C.A. No. 19-18564, ECF No. 16 (D.N.J. Dec. 23, 2019); *Mitsubishi Tanabe Pharma Corp., et al., v. MSN Labs. Private Ltd., et al.*, C.A. No. 19-15616, ECF No. 10 (D.N.J. Oct. 22, 2019); *BTG Int'l Ltd., et al., v. MSN Pharms. Inc., et al.*, C.A. No. 18-02372, ECF No. 8 (D.N.J. June 8, 2018); *Merck Sharp & Dohme Corp. v. MSN Labs. Private Ltd., et al.*, C.A. No. 18-00675, ECF No. 17 (D.N.J. Mar. 28, 2018); *Forest Labs., LLC, et al., v. MSN Labs. Private Ltd., et al.*, C.A. No. 17-10140, ECF No. 14 (D.N.J. Dec. 6, 2017); *Boehringer Ingelheim Pharms., Inc., et al., v. MSN Labs. Private Ltd., et al.*, C.A. No. 17-08399, ECF No. 12 (D.N.J. Jan. 2, 2018); *Boehringer Ingelheim Pharms., Inc., et al., v. Aurobindo Pharma USA Inc., et al.*, C.A. No. 17-07887, ECF No. 55 (D.N.J. June 26, 2018); *Mitsubishi Tanabe Pharma Corp., et al., v. MSN Labs. Private Ltd., et al.*, C.A. No. 17-05302, ECF No. 47 (D.N.J. Dec. 22, 2017); *Sumitomo Dainippon Pharma Co., Ltd., et al., v. MSN Labs. Private Ltd., et al.*, C.A. No. 17-01010, ECF No. 33 (D.N.J. May 11, 2018); *Boehringer Ingelheim Pharms., Inc., et al., v. Hec Pharm Group, et al.*, C.A. No. 15-05982, ECF No. 55 (D.N.J. Sep. 3, 2015); *Janssen Prods., L.P., et al. v. MSN Pharms. Inc. and MSN Labs. Private Ltd.*, C.A. No. 21-14622, ECF No. 15 (D.N.J. Dec. 17, 2021).

22. Defendants have not contested personal jurisdiction in this Judicial District, including in patent infringement actions under the Hatch-Waxman Act. *See, e.g., Bausch Health Ireland Ltd., et al., v. MSN Labs. Private Ltd., et al*., C.A. No. 21-10057, ECF No. 10 (D.N.J. June 18, 2021); *Actelion Pharms. Ltd., et al., v. MSN Pharms. Inc., et al*., C.A. No. 20-03859, ECF No.

16 (D.N.J. June 3, 2020); *Mitsubishi Tanabe Pharma Corp., et al., v. MSN Labs. Private Ltd., et al*., C.A. No. 19-18958, ECF No. 11 (D.N.J. Dec. 6, 2019); *Chiesi USA Inc., et al., v. MSN Pharms. Inc., et al.*, C.A. No. 19-18564, ECF No. 16 (D.N.J. Dec. 23, 2019); *Mitsubishi Tanabe Pharma Corp., et al., v. MSN Labs. Private Ltd., et al*., C.A. No. 19-15616, ECF No. 10 (D.N.J. Oct. 22, 2019); *BTG Int'l Ltd., et al., v. MSN Pharms. Inc., et al.*, C.A. No. 18-02372, ECF No. 8 (D.N.J. June 8, 2018); *Merck Sharp & Dohme Corp. v. MSN Labs. Private Ltd., et al*., C.A. No. 18-00675, ECF No. 17 (D.N.J. Mar. 28, 2018); *Forest Labs., LLC, et al., v. MSN Labs. Private Ltd., et al.*, C.A. No. 17-10140, ECF No. 14 (D.N.J. Dec. 6, 2017); *Boehringer Ingelheim Pharms., Inc., et al., v. MSN Labs. Private Ltd., et al.*, C.A. No. 17-08399, ECF No. 12 (D.N.J. Jan. 2, 2018); *Boehringer Ingelheim Pharms., Inc., et al., v. Aurobindo Pharma USA Inc., et al.*, C.A. No. 17-07887, ECF No. 55 (D.N.J. June 26, 2018); *Mitsubishi Tanabe Pharma Corp., et al., v. MSN Labs. Private Ltd., et al.*, C.A. No. 17-05302, D.I. 47 (D.N.J. Dec. 22, 2017); *Sumitomo Dainippon Pharma Co., Ltd., et al., v. MSN Labs. Private Ltd., et al.*, C.A. No. 17-01010, ECF No. 33 (D.N.J. May 11, 2018); *Boehringer Ingelheim Pharms., Inc., et al., v. Hec Pharm Group, et al.*, C.A. No. 15-05982, ECF No. 55 (D.N.J. Sep. 3, 2015); and *Janssen Prods., L.P., et al. v. MSN Pharms. Inc. and MSN Labs. Private Ltd.*, C.A. No. 21-14622, ECF No. 15 (D.N.J. Dec. 17, 2021); *Celgene Corp. v. MSN Labs. Private Ltd., et al.*, C.A. No. 22-01993 (D.N.J. Apr. 6, 2022).

23. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

CATALYSTS FYCOMPA (PERAMPANEL) PRODUCT

24. Catalyst is the holder of NDA No. 208277, by which FDA granted approval for perampanel 0.5mg/ML oral suspension. Catalyst markets these tablets in the United States under the tradename Fycompa. NDA No. 208277 was formerly filed and held by Eisai Inc.

PATENT-IN-SUIT

25. Catalyst is the owner of United States Patent No. 8,772,497, which was duly and legally issued on July 8, 2014, and is titled "Method for Producing 1,2-Dihydropyridine-2-One Compound." Each and every claim of the '497 patent is valid and enforceable. A copy of the '497 patent is attached as Exhibit 1.

26. The '497 patent claims, *inter alia*, crystalline forms of perampanel and processes for the production of crystalline forms of perampanel.

27. Claim 4 of the '497 patent reads as follows:

> A crystal of 3-(2-cyanophenyl)-5-(2-pyridyl)-1-phenyl-1,2-dihydropyridin-2-one hydrate having an absorption peak at a wavenumber of 1588±1 cm^{-1} in an infrared absorption spectrum (KBr method).

28. Claim 5 of the '497 patent reads as follows:

> A crystal of 3-(2-cyanophenyl)-5-(2-pyridyl)-1-phenyl-1,2-dihydropyridin-2-one hydrate having absorption peaks at wavenumbers of 1588±1 cm^{-1} and 751±1 cm^{-1} in an infrared absorption spectrum (KBr method).

29. The drug compound 3-(2-cyanophenyl)-5-(2-pyridyl)-1-phenyl-1,2-dihydropyridin -2-one hydrate is known as perampanel.

ACTS GIVING RISE TO THIS ACTION

30. By letter dated February 17, 2023 (the "Notice Letter"), Defendants notified Catalyst that it had submitted to FDA Defendants' ANDA, seeking approval for the commercial manufacture, use, and sale of Defendants' ANDA Product in the United States prior to the expiration of the Patent-in-Suit.

31. In the Notice Letter, Defendants notified Catalyst that, as a part of Defendants' ANDA, it had filed a certification under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §

355(j)(2)(A)(vii)(IV) with respect to the Patent-in-Suit, asserting that the Patent-in-Suit is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Defendants' ANDA Product in the United States.

32. By filing Defendants' ANDA, Defendants have necessarily represented to FDA that, upon approval, Defendants' ANDA Product will have the same active ingredient, method of administration, dosage form, and strength as Fycompa, and will be bioequivalent to Fycompa.

33. Fycompa is covered by one or more claims of the Patent-in-Suit.

34. FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") lists the Patent-in-Suit in connection with Fycompa.

35. The Complaint has been filed before the expiration of forty-five days from the date Catalyst received the Notice Letter.

COUNT I: INFRINGEMENT OF THE '497 PATENT

36. Catalyst realleges paragraphs 1-35 as if fully set forth herein.

37. On information and belief, and according to Defendants' ANDA, Defendants' Proposed ANDA Product contains crystalline forms of perampanel that have all limitations of at least claims 4 and 5, literally or under the doctrine of equivalents.

38. Defendants' Notice Letter does not allege that Defendants' ANDA Product will not infringe the claims of the '497 patent and does not identify limitations of those claims that are not present in Defendants' ANDA Product.

39. Defendants' submission of Defendants' ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Defendants' ANDA Product in or into the United States, prior to the expiration of the '497 patent, constitutes direct and indirect infringement of the '497 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

40. On information and belief, Defendants' manufacturing, use, offer for sale, sale, and/or importation of Defendants' ANDA Product, once Defendants' ANDA is approved by FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '497, either literally or under the doctrine of equivalents.

41. Catalyst will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Defendants' ANDA Product in or into the United States, and are not enjoined from doing so. Catalyst is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of Defendants' ANDA be a date that is not earlier than the expiration date of the '497 patent, or any later expiration of exclusivity for the '497 patent to which Catalyst is or becomes entitled, and an injunction against such infringement. Catalyst does not have an adequate remedy at law.

42. Defendants have had knowledge of the '497 patent since at least the date Defendants submitted Defendants' ANDA and were aware that submission of Defendants' ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

43. This case is "exceptional," and Catalyst is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Catalyst prays that this Court grant the following relief:

(a) A judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '497 patent through Defendants' submission of ANDA No. 217996 to FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Defendants' ANDA Product before the expiration of the '497 patent;

(b) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Defendants'

commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Defendants' ANDA Product before the expiration of the '497 patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '497 patent;

(c) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Defendants' ANDA, shall not be earlier than the latest expiration date of the Patent-in-Suit, including any extensions and/or additional periods of exclusivity to which Catalyst is or becomes entitled;

(d) The entry of a permanent and/or preliminary injunction enjoining Defendants, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, having made, using, offering to sell, selling, marketing, distributing, and importing in or into the United States Defendants' ANDA Product, or any product that infringes the Patent-in-Suit, or inducing or contributing to the infringement of the Patent-in-Suit until after the latest expiration date of the Patent-in-Suit, including any extension and/or additional periods of exclusivity to which Catalyst is or becomes entitled, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(e) The entry of a permanent and/or preliminary injunction enjoining Defendants, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from seeking, obtaining, or maintaining approval of Defendants' ANDA until the expiration of the Patent-in-Suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(f) Damages or other monetary relief to Catalyst if Defendants engage in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of Defendants' ANDA Product prior to the expiration of the latest expiration date of the Patent-in-

Suit, including any extensions and/or additional periods of exclusivity to which Catalyst is or becomes entitled;

(g) A finding that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Catalyst its attorney's fees incurred in this action; and

(h) Such further relief as this Court deems proper and just.

Dated: April 5, 2023

By: /s/ Charles H. Chevalier

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